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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR               | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|------------------------------------|---------------------|------------------|
| 10/035,833   | 12/27/2001  | Yusuke Nakamura                    | FORS-06904          | 2659             |
| 7590 06/08/2004  |             |                                    |                     |                  |
| MEDLEN & CARROLL, LLP<br>101 Howard Street, Suite 350<br>San Francisco, CA 94105 |             | EXAMINER<br>SITTON, JEHANNE SOUAYA |                     |                  |
|  |             | ART UNIT PAPER NUMBER              |                     |                  |
|  |             | 1634                               |                     |                  |

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/035,833

Applicant(s)

NAKAMURA ET AL.

Examiner

Jehanne Souaya Sitton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-123 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-123 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 23-29, 31-36, 44-45, and 113-123, drawn to nucleic acid sequences containing SNPs, vectors and host cells comprising such, classified in class 536, subclass 23.1, class 435, subclass 325, and class 435, subclass 325 respectively.
  - II. Claim 30, drawn to polypeptides, classified in class 530, subclass 350.
  - III. Claims 1-22, 37-41, and 76-110, drawn to methods of identifying individuals having a polymorphism using nucleic acid based assays, classified in class 435, subclass 6.
  - IV. Claims 46-75, drawn to methods for determining side effect or effectiveness of drugs, classified in class 435, subclass 6.
  - V. Claims 111-112, drawn to methods for generating assay data sets and the data sets generated by the method, classified in class 435, subclass 6.

\*It is noted that claims 42 and 43 are drawn to compositions but the claim limitations are drawn to methods, as such, the examiner is unable to classify and therefore determine which group these claims belong. Therefore, these claims are not considered until clarification is made.

2. The inventions are distinct, each from the other because of the following reasons:

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The inventions of groups I and II are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of group I is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptide of group II is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. The products of groups I and II can be used in materially different processes, for example the DNA of group I can be used in hybridization assays, and the polypeptide of group II can be used to make a fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I and II are patentably distinct from each other.

3. Inventions II and III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different effects and different functions. The polypeptide of group II is not required to practice the methods of any of groups III-V.

4. The inventions of groups I and groups III-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of groups I can be used to encode proteins which is not required for any of the methods of groups III-V.

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5. The inventions of groups III-V are patentably distinct from each other. The methods of detecting polymorphism, methods of treating, and methods of generating data do not require the same reagents, reaction parameters or reaction conditions. Additionally, the methods are unobvious over one another.

6. Additionally, each group named above is subject to further restriction. Applicant is required to further elect either a specific SEQ ID NO drawn to a particular gene or up to 5 specific SEQ ID NOS that are drawn to the same gene. In making this restriction requirement, the examiner assumes that each SEQ ID NO: in the sequence listing contains a single SNP. Up to 5 sequences comprising a SNP will be searched and examined in the alternative, as long as they are sequences that are from the same gene. Searching more than 5 SNPs to a single gene represents a search burden for the office. If applicant wishes to do so, applicant is requested to indicate the 5 SEQ ID NOS comprising SNPs from the same gene. Alternatively, if applicant wishes to elect a composition comprising a specific set of SEQ ID NOS (not necessarily from the same gene), applicant may do so and is requested to indicate the specific combination of SEQ ID NOS. This is NOT an election of species. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, “[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.” 35 U.S.C. 121. Pursuant to this statute, the rules provide that “[i]f two or

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more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted.”

37 CFR 1.142 (a). See also 37 CFR 1.141(a). It is noted that searching more than 5 of the claimed patentably distinct sequences represents a serious burden for the office.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-V and the search of SEQ ID NO: 1 is not required for any of the other listed SEQ ID NOS, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-

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0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (571) 272-0507.



Jehanne Sitton  
Primary Examiner  
Art Unit 1634

6/7/04